PMDA Updates

November 2010

< NEWS >

1) MHLW/PMDA exchange Confidentiality Arrangement Statement with Swissmedic : November 7, 2010

MHLW/PMDA extended its international networking activities and exchanged confidentiality arrangement statement with Swissmedic - Swiss Agency for Therapeutic Products on November 7, 2010. The arrangement is expected to enhance cooperation, collaboration, and information sharing between the two countries.

2) International Conference on Harmonization (ICH) Meeting held in Fukuoka, Japan : November 6 -11, 2010

The International Conference on Harmonization (ICH) Steering Committee（SC）and its Expert Working Groups (EWGs) met in Fukuoka, Japan, November 6 -11 2010. The ICH SC endorsed the opening of the ICH technical working groups to the active participation of experts from qualifying members of the Global Cooperation Group (GCG). This meeting marked the 20th anniversary of the International harmonization initiative. ICH published a brochure entitled “The value and benefit of ICH to drug regulatory authorities advancing harmonization for public health” in recognition of the anniversary. Progress includes Annex 7 (R2) on Dissolution Test for the ICH Q4B guideline reaching Step 4. The next meeting will be held in Cincinnati, Ohio, USA from June 11-16, 2011.

3) Additional Measures recommended by the Government Revitalization Unit (GRU) to further improve PMDA Operations: November 17, 2010

A working group of GRU established to reform the overall national administration reviewed PMDA’s business program. The WG concluded that the previous evaluation results regarding the agency’s review and safety services have not been fully reflected in the management. The WG also suggested improvement in PMDA’s governance, through securing human resources in an efficient manner and focusing more on PMDA’s core services.

4) PMDA offer Training Program for JICA Chinese Administrative Officers: November 24, 2010

PMDA provided a special training program covering Japanese review system of vaccine,

safety measures on vaccine preparations and relief services for the vaccine adverse reactions, to the Chinese government officials and exchanged opinions with them.

5) Training of Korea Food and Drug Administration (KFDA) Reviewers/Experts in New drugs, Generics and Pharmacovigilance : from November 24 to December 21, 2010

PMDA accepted three technical trainees from the Korean agency, who are reviewers or analysts dealing with review of new drugs as well as generics, and pharmacovigilance, November 24 to December 21, 2010. PMDA provided the specialized technical training programs by assigning trainees to related offices. The trainees will report their achievements to whole PMDA in the reporting session on December 21, 2010.

6) The First PMDA Training Seminar successfully completed: November 29 - December 3, 2010.

The PMDA Training Seminar designed for officials who are reviewing drugs / biologics was successfully completed. The main purpose of the inaugural Seminar was to provide attendees with an overview of the PMDA's functions as well as accounts on various aspects of scientific review process of New Drug and post-marketing safety measures, to show how PMDA's review assures safety, efficacy and quality of drugs approved. The Seminar enjoyed vigorous Q&A sessions and exchange of views. The trainees were from five Asian countries: Indonesia, South Korea, China, Singapore and Taiwan.

< Safety Information >

●Pharmaceuticals and Medical Devices Safety Information No.273, October 2010

The articles in this issue describe the following information.

- The Relief System for Sufferers from Adverse Drug Reactions and Diseases Infected from Biological Products
- Summary of the Report on Adverse Reactions Associated with the Influenza A (H1N1) Vaccines in the 2009 Season
- Important Safety Information [Influenza HA Vaccine, Influenza A (H1N1) HA Vaccine, Influenza A (H1N1) HA Emulsion Vaccine, Cell-culture Derived Influenza A (H1N1) Emulsion HA Vaccine and Thalidomide]
- List of Products Subject to Early Post-marketing Phase Vigilance
- Reference: Reports on adverse reactions associated with seasonal influenza vaccines in FY 2009 (Conclusion of the Vaccine Adverse Reaction Review Committee)

For more details: http://www.pmda.go.jp/english/service/pdf/precautions/PMDSI-273.pdf

< Events >

1. Conferences/meetings PMDA hosts

Date	Title	Location
December 24	Reporting Session “ the latest trend of EMA and its current status on International collaboration” (Mr Yoshikazu Hayashi, International liaison officer and Mr.Shinobu Uzu, International Planning Director, MHLW)	PMDA’s Office

2. **Conferences/meetings PMDA participates in**

Date	Title	Location
December 7-8	ASEAN Working Group on Pharmaceutical Development (AWGPD)	Bangkok, Thailand